JAN 1 8 2002

# 510(k) Summary for N Latex Lp(a) Reagent

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013128

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

| | |
|---|---|
| Manufacturer: | Dade Behring Marburg GmbH<br>Emil-von-Behring Str. 76<br>Marburg/Germany |
| Contact Information: | Dade Behring Inc.<br>Glasgow Site<br>P.O. Box 6101<br>Newark, Delaware 19714<br>Attn: Rebecca S. Ayash<br>Tel: 302-631-6276 |
| Preparation date: | January 4, 2002 |

**2. Device Name/ Classification:**

| | |
|---|---|
| **N Latex Lp(a) Reagent:** | Low-density lipoprotein immunological test system, Class II (866.5600) |
| **Product Code:** | 81 DFC |

**3. Identification of the Legally Marketed Device:**

Beckman Coulter Array® System LPA assay (K000121)

**4. Device Description:**

Polystyrene latex particles coated with specific antibodies to human Lp(a) are agglutinated when mixed with samples containing Lp(a). The intensity of scattered light in the BN™ Systems depends on the Lp(a) concentration in the sample. The concentration can therefore be determined by comparison with dilutions of a standard of known concentration.

5. **Device Intended Use:**

N Latex Lp(a) is an *in vitro* diagnostic reagent for the quantitative determination of lipoprotein(a) [Lp(a)] in human serum and heparinized plasma by means of particle enhanced immunonephelometry using BN™ Systems. Measurement of Lp(a) aids in the identification of individuals at risk from cardiovascular disease in specific populations when used in conjunction with clinical evaluation.

6. **Medical device to which equivalence is claimed and comparison information:**
There are a number of *in vitro* diagnostic products in commercial distribution, which employ immunoassay techniques for the quantitative determination Lp(a) in human serum or plasma. One such product is the Beckman Coulter Array® System LPA assay (K000121). The N Latex Lp(a) Reagent is substantially equivalent in intended use and results obtained to the Array®System LPA assay. The N Latex Lp(a) Reagent, like the Array® System LPA assay is intended to be used for the quantitative determination of Lp(a) activity in human serum or plasma.

7. **Device Performance Characteristics:**

**Correlation:**

The N Latex Lp(a) assay was compared to a commercially available Lp(a) immunonephelometric method by evaluating 86 laboratory serum samples ranging from 0.02 to 1.31 g/L. A correlation coefficient of 0.96 was obtained with a y-intercept value of –0.005 and a slope of 0.92 (Passing-Bablok).

**Precision:**

The N Latex Lp(a) Reagent was used to measure the N Lp(a) Control SY and 6 patient samples or pools with Lp(a) concentrations between 0.29 and 1.77 g/L and yielded coefficients of variation between 1.8 and 4.1% for the intra-assay precision (n=20). N Lp(a) Control SY and 5 patient samples or pools with Lp(a) concentrations between 0.17 and 1.75 g/L were used to determine the inter-assay reproducibility (n=10) and the coefficients of variation were between 2.8 and 5.3%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 8 2002

Ms. Kathleen A. Dray-Lyons
Manager, Regulatory Affairs
Dade Behring Inc.
Glasgow Site, P.O. Box 6101
Newark, DE 19714

Re: k013128
Trade/Device Name: N Latex Lp (a) Reagent
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: DFC
Dated: January 4, 2002
Received: January 7, 2002

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 013128

# Indications Statement

**Device Name:** N Latex Lp(a) Reagent

**Indications for Use:**

N Latex Lp(a) Reagent is an *in vitro* diagnostic test for the quantitative determination of Lipoprotein(a) [Lp(a)] in human serum or plasma. N Latex Lp(a) aids in the diagnosis of disorders of lipid (fat) metabolism and helps to identify persons at risk from cardiovascular disease in specific populations when used in conjunction with clinical evaluation.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 013128

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)